

Form PTO-1449 (modified)

Atty. Docket No.

Serial No.

INRP:050/GNS #34

08/918,407

List of Patents and Publications for Applicant's

Applicant

Jack A. Roth *et al.*

## INFORMATION DISCLOSURE STATEMENT

Filing Date:

Group:

August 26, 1997

1636

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Patent Documents

Foreign Patent Documents

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
<i>Q</i>	A12	4,920,209	4/24/90	Davis <i>et al.</i>	<del>435</del>	235	

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
<i>Q</i>	B24	WO 93/19191	9/30/93	PCT			
<i>Q</i>	B25	WO 95/11301	4/27/95	PCT			
<i>Q</i>	B26	8-508879	9/24/96	Japan			

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Exam. Init.	Ref. Des.	Citation
<i>Q</i>	C251	Eaves <i>et al.</i> , "The biology of normal and neoplastic stem cells in CML," Chronic Myeloid Leukemia, 2 <sup>nd</sup> Int'l Conference, Bologna, Italy, October 4-7, 1992. From <i>Leukemia and Lymphoma</i> , 11:245-253 (1993).
<i>Q</i>	C252	Felgner <i>et al.</i> , "Lipfection: a highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> , 84:7413-7417, 1987.
<i>Q</i>	C253	Gjerset <i>et al.</i> , "Dominant effect of transduced wild-type p53 over endogenous mutant p53 in sensitizing tumor cells to therapy," <i>Proceedings of the Am. Assoc. Can. Res.</i> , 36:21, 1995. (Abstract 123)
<i>Q</i>	C254	Gomez-Navarro <i>et al.</i> , "Gene Therapy for Cancer," <i>European Journal of Cancer</i> , 35:867-885, 1999.
<i>Q</i>	C255	Green, "When the Products of Oncogenes and Anti-Oncogenes Meet," <i>Cell</i> , 56:1-3, 1989.
<i>Q</i>	C256	Harper <i>et al.</i> , "the p21 cdk-interacting protein cip1 is a potent inhibitor of g1 cyclin-dependent kinases," <i>Cell</i> , 75:805-816, 1993.
<i>Q</i>	C257	Harper <i>et al.</i> , "Enhancement of antitumor effects of p53 gene therapy by combination with DNA-damaging agents," <i>Cancer Gene Therapy</i> , Vol. 3, 6, Conf. Suppl., S41-42, 1996.

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*William Smith*

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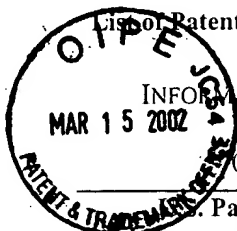
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








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	C258	<i>Hematology/Oncology Clinics of North America</i> , v. 4, n. 3, <i>Bone Marrow Transplantation</i> , edited by Stephen J. Foreman, M.D., 1990.
	C259	Hinds, "Biological Consequences of mutation of the p53 proto-oncogene," <i>UMI Dissertation Services</i> , October 1989.
	C260	Huber <i>et al.</i> , "Retroviral-Mediated Gene Therapy for the Treatment of Hepatocellular Carcinoma: An Innovative Approach for Cancer Therapy," <i>Proc. Natl. Acad. Sci. USA</i> , 88:8039-8043, 1991.
	C261	Kastan "p53 and other molecular controls of the response to DNA damage," <i>Adv. Exp. Med. Biol.</i> , 339:295-296, 1993.
	C262	Kastan, "Discussion of Dr. Kastan's presentation," <i>Adv. Exp. Med. Biol.</i> , 339:295-296, 1993.
	C263	Klinken <i>et al.</i> , "Transcriptional and Post-Transcriptional Regulation of C-MYC C-MYB and p53 During Proliferation and Differentiation of Muring Erythroleukemia Cells Treated with DFMO and DMSO," <i>Exp. Cell Res.</i> , 178:185-198, 1988.
	C264	Kriegler <i>et al.</i> , In: <i>Gene Transfer and Expression: a laboratory manual</i> , 1990.
	C265	Lord <i>et al.</i> , "Macrophage Inflammatory Protein: Its Characteristics, Biological Properties and Role in the Regulation of Haemopoiesis," <i>International J. of Hematology</i> , 57:197-206, 1993.
	C266	Marx, "Cell Death Studies Yield Cancer Clues," <i>Science</i> , 259:760-761 (1993).
	C267	Orazi <i>et al.</i> , "Frequent p53 overexpression in therapy related myelodysplastic syndromes and acute myeloid leukemias: an immunohistochemical study of bone marrow biopsies," <i>Mod. Path.</i> , 6:521-525, 1993.
	C268	Ryan <i>et al.</i> , "Cell Cycle Analysis of p53-Induced Cell Death in Murine Erythroleukemia Cells," <i>Mol. Cell. Biol.</i> , 13:711-719, 1993.
	<del>C269</del>	<del>Stratagene Catalogue, page 39, 1988.</del> <i>Previously cited in 872</i>
	C270	Weinberg, "Tumor Suppressor Genes," <i>Science</i> , 254:1138-1146, 1991.

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*William S. Sabel*

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Serial No.  
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List of Patents and Publications for Applicant's

Applicant  
Jack A. Roth *et al.*

INFORMATION DISCLOSURE STATEMENT

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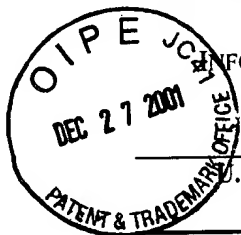
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Foreign Patent Documents

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OK	B23	WO 94/26914	11/24/94	PCT			

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OK	C249	Fan <i>et al.</i> , "p53 gene mutations are associated with decreased sensitivity of human lymphoma cells to DNA damaging agents," <i>Cancer Res.</i> , 54(22):5824-5830, 1994.
OK	C250	Fujiwara <i>et al.</i> , "Induction of chemosensitivity in human lung cancer cells in vivo by adenovirus-mediated transfer of the wild-type p53 gene," <i>Surgical Forum</i> , 45:524-526, 1994.

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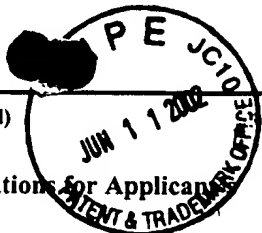
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<i>Q</i>	C271	Gobe <i>et al.</i> , "Cell death by apoptosis following X-irradiation of the foetal and neonatal rat kidney," <i>Int. J. Radiat. Biol.</i> , 54:567-576, 1988.
<i>B</i>	C272	Ijiri, "Apoptosis (cell death) induced in mouse bowel by 1,2-dimethylhydrazine, methylazoxymethanol acetate and $\gamma$ -rays," <i>Cancer Research</i> , 49:6342-6346, 1989.
<i>h</i>	C273	Zhang <i>et al.</i> , "High-efficiency gene transfer and high-level expression of wild-type p53 in human lung cancer cells mediated by recombinant adenovirus," <i>Cancer Gene Therapy</i> , 1:5-13, 1994.

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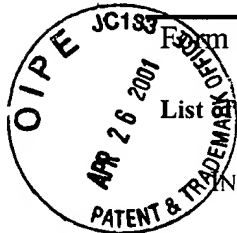
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<i>CH</i>	A7	5,362,623	11/08/94	Vogelstein <i>et al.</i>	485	6	RECEIVED APR 30 2001 TECH CENTER 1600/2900
<i>CH</i>	A8	5,496,731	3/5/96	Xu, <i>et al.</i>	435	320.1	
<i>CH</i>	A9	5,527,676	6/18/96	Vogelstein <i>et al.</i>	435	6	
<i>CH</i>	A10	5,585,362	12/17/96	Wilson <i>et al.</i>	514	44	
<i>CH</i>	A11	6,090,566	07/18/00	Vogelstein <i>et al.</i>	435	7.23	

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
<i>CH</i>	B14	WO 90/05180	5/17/90	PCT			
<i>CH</i>	B15	WO 91/15580	10/17/91	PCT			
<i>CH</i>	B16	WO 94/18992	9/1/94	PCT			
<i>CH</i>	B17	WO 95/14101	5/26/95	PCT			
<i>CH</i>	B18	WO 95/14102	5/26/95	PCT			
<i>CH</i>	B19	WO 95/23867	9/8/95	PCT			

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Exam. Init.	Ref. Des.	Citation
	<del>C167</del>	<del>Anderson, "Human Gene Therapy," <i>Nature</i>, 392:25-30, April 30, 1998.</del>
		<i>listed on previous 892</i>
<i>CH</i>	C168	Baker <i>et al.</i> , "p53 Gene Mutations Occur in Combination with 17p Allelic Deletions as Late Events in Colorectal Tumorigenesis," <i>Cancer Research</i> , 50:7717-7722, December 1990.

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	<del>C169</del> ✓	<del>Baker et al., "Suppression of Human Colorectal Carcinoma Cell Growth by Wild-Type p53," Science, 249:912-915, August 1990.</del> not provided
<i>JP</i>	C170	Chang et al., "Inhibition of intratracheal lung cancer development by systemic delivery of E1A," <i>Oncogene</i> , 13:1405-1412, 1996.
<i>JP</i>	C171	Carter et al., "Adenovirus Containing a Deletion of the Early Region 2A Gene Allows Growth of Adeno-Associated Virus with Decreased Efficiency," <i>Virology</i> , 191:473-476, 1992.
<i>M</i>	C172	Chang et al., "Restoration of the G1 Checkpoint and the Apoptotic Pathway Mediated by Wild-type p53 Sensitizes Squamous Cell Carcinoma of the Head and Neck to Radiotherapy," <i>Arch Otolaryngol Head Neck Surg.</i> , 123:507-512, 1997.
<i>JP</i>	C173	Colicos et al., "Construction of a recombinant adenovirus containing the <i>denV</i> gene from bacteriophage T4 which can partially restore the DNA repair deficiency in xeroderma pigmentosum fibroblasts," <i>Carcinogenesis</i> , 12(2):249-255, 1991.
<i>JP</i>	C174	Cai et al., "Stable expression of the wild-type p53 gene in human lung cancer cells after retrovirus-mediated gene transfer," <i>Hum. Gene Ther.</i> , 4:617-24, 1993.
<i>JP</i>	C175	Davidson et al., "A model system for in vivo gene transfer into the central nervous system using adenoviral vector," <i>Nature Genetics</i> , 3:219-223, 1993.
<i>JP</i>	C176	Delauney et al., "A Stable Bifunctional Antisense Transcript Inhibiting Gene Expression in Transgenic Plants," <i>Proc. Natl. Acad. Sci. USA</i> , 85:4300-4304, 1988.
<i>JP</i>	C177	Dorigo et al., "Sensitization of rat glioblastoma multiforme to cisplatin in vivo following restoration of wild-type p53 function," <i>J. Neurosurg.</i> , 88:535-540, 1998.
<i>JP</i>	C178	Eliyahu et al., "p53 - A potential suppressor gene?" <i>J. Cell. Biochem.</i> , UCLA Symposia on Molecular and Cellular Biology, Abstracts, 19 <sup>th</sup> Annual Meeting, Supplement 14C:264, #1 030, 1990.
<i>JP</i>	C179	Eliyahu et al., "Meth A Fibrosarcoma Cells Express Two Transforming Mutant p53 Species," <i>Oncogene</i> , 3:313-321, 1988.
<i>JP</i>	C180	Eliyahu et al., "Wild-type p53 Can Inhibit Oncogene-Mediated Focus Formation," <i>Proc. Nat. Acad. Sci. USA</i> , 85:8763-8767, November 1989.

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Exam. Init.	Ref. Des.	Citation
<i>D</i>	C181	Finlay <i>et al.</i> , "The p53 Proto-Oncogene Can Act as a Suppressor of Transformation," <i>Cell</i> , 57:1083-1093, June 1989.
<i>D</i>	C182	Fox; "Investigation of gene therapy begins," <i>Nature Biotechnology</i> , 18:143-144, 2000.
<i>M</i>	C183	Fujiwara <i>et al.</i> , "Therapeutic effect of a retroviral wild-type p53 expression vector in an orthotopic lung cancer model," <i>J. Natl. Cancer Inst.</i> , 86(19):1458-1462, 1994.
<i>M</i>	C184	Gebhardt <i>et al.</i> , "A Tumor Suppressor Proto-Oncogene p53 Can Block Progression Through the Cell Cycle," Association of American Physicians, American Society for Clinical Investigation, American Federation for Clinical Research, Subspecialty Meetings, Sheraton Washington Hotel, Washington, DC, May 6, 1990, pg. 447A, Abstract.
	<del>C185</del>	<del>Friedmann, "Gene therapy of cancer through restoration of tumor-suppressor functions?," <i>Cancer Suppl.</i>, 70(6):1810-1817, 1992</del> <i>Not provided</i>
<i>M</i>	C186	Georges, <i>et al.</i> , "Prevention of Orthotopic Human Lung Cancer Growth by Intratracheal Instillation of a Retroviral Antisense K-ras Construct," <i>Cancer Research</i> , 53:1743-1746, 1993.
<i>M</i>	C187	Gomez-Foix, <i>et al.</i> , "Adenovirus-Mediated Transfer of the Muscle Glycogen Phosphorylase Gene into Hepatocytes Confers Altered Regulation of Glycogen Metabolism," <i>The Journal of Biological Chemistry</i> , 267(35):25129-25134, 1992.
	<del>C188</del>	<del>Gregory, <i>et al.</i>, "Tumor Suppressor of Gene Therapy of Cancer: Adenoviral-Mediated Gene Transfer of p53 into Human Tumor Cell Lines," <i>J. Cell. Biochem. Suppl.</i> 18a, p. 237.</del> <i>Not provided</i>
<i>M</i>	C189	Gridley <i>et al.</i> , "Evaluation of radiation effects against C6 glioma in combination with vaccinia virus-p53 gene therapy," <i>International J. Oncology</i> , 13:1093-1098, 1998.
<i>M</i>	C190	Gutierrez <i>et al.</i> , "Gene Therapy for Cancer," <i>The Lancet</i> , 339:715-721, 1992.
<i>M</i>	C191	Hanania <i>et al.</i> , "Genetic chemoprotection of hematopoietic cells and genetic chemosensitization of breast cancer cells in a mouse cancer gene therapy model," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 37, #2362, March 1996.
<i>M</i>	C192	Hinds <i>et al.</i> , "Mutation is Required to Activate the p53 Gene for Cooperation with the ras Oncogene and Transformation," <i>Journal of Virology</i> , 63(2):739-746, February 1989.

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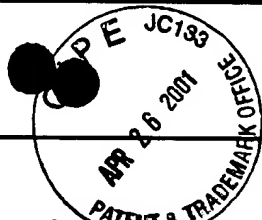
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<i>CS</i>	C193	Hinds <i>et al.</i> , "The p53 Proto-Oncogene Can Suppress Transformation by Other Oncogenes, and Mutations in the Proto-Oncogene Can Activate the Gene for Transformation," <i>In: Common Mechanisms of Transformation by Small DNA Tumor Viruses</i> , Luis P. Villarreal (ed.), Chapter 7, pp. 83-101, 1989.
<i>CS</i>	C194	Hitt <i>et al.</i> , "Adenovirus E1A under the Control of Heterologous Promoters: Wide Variation in E1A Expression Levels Has Little Effect on Virus Replication," <i>Virology</i> , 179:667-678, 1990.
<i>CS</i>	C195	Hodgson, "Advances in Vector Systems for Gene Therapy," <i>Exp. Opin. Ther. Patents</i> , 5(5):459-468, 1995
<i>CS</i>	C196	Hollstein <i>et al.</i> , "p53 Mutations in Human Cancers," <i>Science</i> , 253:49-53, 1991.
<i>CS</i>	C197	Huang <i>et al.</i> , "Suppression of the Neoplastic Phenotype by Replacement of the RB Gene in Human Cancer Cells," <i>Science</i> , 242:1563-1566, December 1988.
<i>CS</i>	C198	Jaffe <i>et al.</i> , "Adenovirus-Mediated <i>In Vivo</i> Gene Transfer and Expression in Normal Rat Liver," <i>Nature Genetics</i> , 1:372-378, 1992.
<i>CS</i>	C199	Klessig <i>et al.</i> , "Introduction, Stable Integration, and Controlled Expression of a Chimeric Adenovirus Gene Whose Product is Toxic to the Recipient Human Cell," <i>Molecular and Cellular Biology</i> , 4(7): 1354-1362, July 1984.
<i>CS</i>	C200	Kmieciak, "Investigators have been searching for ways to add corrective genes to cells harboring defective genes. A better strategy might be to correct the defects." <i>American Scientist</i> , 87:240-247, 1999.
<i>CS</i>	C201	Lamb and Crawford, "Characterization of the Human p53 Gene," <i>Molecular and Cellular Biology</i> , 6(5):1379-1385, May 1986.
<i>CS</i>	C202	Le Gal La Salle <i>et al.</i> , "An Adenovirus Vector for Gene Transfer into Neurons and Glia in the Brain," <i>Science</i> , 259:988-990, 1993.
<i>CS</i>	C203	Lee <i>et al.</i> , "Molecular basis of tumor suppression by the human retinoblastoma gene," <i>UCLA Symposia on Molecular and Cellular Biology, Abstracts</i> , 19 <sup>th</sup> Annual Meeting, Supplement 14C, #I 001, 1990.

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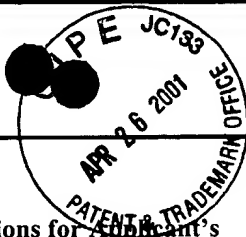
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List of Patents and Publications for Applicant's

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Atty. Docket No.

INRP:050/GNS

Serial No.

08/918,407

Applicant

Jack A. Roth et al.

Filing Date:

August 26, 1997

Group:

1636

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	<del>C207</del>	<del>Lowe <i>et al.</i>, "p53 is Required for Radiation Induced Apoptosis in Mouse Thymocytes," <i>Nature</i> 362:847-849, April 29, 1993.</del> not provided
u	C208	Malkin <i>et al.</i> , "Mutant p53 Confers Tumorigenicity to a Cell Line Lacking p53: Evidence for a Second p53 Function in Tumor Formation," <i>Blood</i> , 76(10, Suppl. 1):238a, Abstract 944, 1990.
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u	C214	Montenarh, "Biochemical, Immunological, and Functional Aspects of the Growth-Suppressor/Oncoprotein p53," <i>Critical Reviews in Oncogenesis</i> , (3):233-256, 1992.

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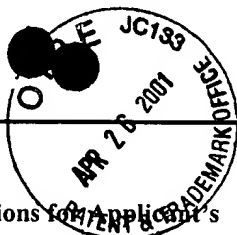
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<i>10</i>	C216	Nielsen <i>et al.</i> , "Efficacy of p53 adenovirus-mediated gene therapy against human breast cancer xenografts," <i>Pro. Annu. Meet. Am. Assoc. Cancer Res.</i> , Vol. 37, pp. A2317, 1996.
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<i>10</i>	C220	Pirollo <i>et al.</i> , "p53 mediated sensitization of squamous cell carcinoma of the head and neck to radiotherapy," <i>Oncogene</i> , 14:1735-46, 1997.
<i>10</i>	C221	Prevec <i>et al.</i> , "Use of Human Adenovirus-Based Vectors for Antigen Expression in Animals," <i>J. Gen. Virol.</i> , 70:429-434, 1989.
<i>10</i>	C222	Rajan <i>et al.</i> , "Simian Virus 40 Small-t Does Not Transactivate RNA Polymerase II Promoters in Virus Infections," <i>J. Virology</i> , 65(12):6553-6561, 1991.
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<i>10</i>	C224	Rosenfeld <i>et al.</i> , "Adenovirus-Mediated Transfer of a Recombinant $\alpha$ 1-Antitrypsin Gene to the Lung Epithelium <i>In Vivo</i> ," <i>Science</i> , 252:431-434, 1991.
<i>10</i>	C225	Rosenfeld <i>et al.</i> , "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium," <i>Cell</i> , 68:143-155, 1992.
<i>10</i>	C226	Ross <i>et al.</i> , "Gene Therapy in the United States: A Five-Year Status Report," <i>Human Gene Therapy</i> , 7:1781-1790, 1996.

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*William Smith*

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	C227	Roth, "Gene Replacement Strategies for Therapy and Prevention of Lung Cancer," <i>Proceedings Annual Meeting of American Assoc. Cancer Res.</i> , 35:692-3, 1994.
	C228	Roth, et al., "Retrovirus-Mediated Wild-Type p53 Gene Transfer to Tumors of Patients with Lung Cancer," <i>Nature Medicine</i> , 2:985-991, 1996
	C229	Sager, "Tumor Suppressor Genes: The Puzzle and the Promise," <i>Science</i> , 246:1406-1412, December 1989.
	C230	Santhanam et al., "Repression of the interleukin 6 gene promoter by p53 and the retinoblastoma susceptibility gene product," <i>Proc. Natl. Acad. Sci. USA</i> , 88:7605-7609, 1991.
	C231	Schuler et al., "A phase I study of adenovirus-mediated wild-type p53 gene transfer in patients with advanced non-small cell lung cancer," <i>Human Gene Therapy</i> , 9:2075-2082, 1998.
	C232	Shenk, "Group C Adenoviruses as Vectors for Gene Therapy," in <i>Viral Vectors</i> , 1995, Academic Press.
	C233	Spitz et al., "Adenoviral mediated p53 gene therapy enhances radiation sensitivity of colorectal cancer cell lines," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 37, #2366, March 1996.
	C234	Stein et al., "Antisense oligonucleotides as therapeutic agents - is the bullet really magical?" <i>Science</i> , 261:1004-1012, 1993.
	C235	Stratford-Perricaudet, "Evaluation of the Transfer and Expression in Mice of an Enzyme-Encoding Gene Using a Human Adenovirus Vector," <i>Human Gene Therapy</i> , 1:241-256, 1990.
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	C239	Takayama et al., "Growth suppression of lung cancer by recombinant adenovirus-mediated human p53 and p21 cDNA transfer," <i>Proceedings Annual Meeting, American Society of Clinical Oncology</i> , 16: A1597, 1997.

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






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Jack A. Roth et al.Filing Date:  
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	C241	Tseng and Brown, "Antisense oligonucleotide technology in the development of cancer therapeutics," <i>Cancer Gene Therapy</i> , 1(1):65-71, 1994.
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	C243	Vogelstein <i>et al.</i> , "Genetic alterations accumulate during colorectal tumorigenesis," UCLA Symposia on Molecular and Cellular Biology, February 3 - March 11, 1990, Abstracts, 19 <sup>th</sup> Annual Meeting, <i>J. Cell. Biochem.</i> , Supplement 14C:264, #1 004, 1990.
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	C245	Wilkinson <i>et al.</i> , "Constitutive and enhanced expression from the CMV major IE promoter in a defective adenovirus vector," <i>Nucleic Acids Research</i> , 20(9):2233-2239, 1992.
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	C247	Xu <i>et al.</i> , "Parental Gene Therapy with p53 Inhibits Human Breast Tumors <i>In Vivo</i> Through a Bystander Mechanism Without Evidence of Toxicity," <i>Human Gene Therapy</i> , 8:177-185, 1997.
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